Food and Drug Administration
[Docket No. 93F-0148]
Albrit & Wilson, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Albrit & Wilson, Ltd. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of tertahydroxymethylphosphonium sulfamate as a stimulant for use in the manufacture of paper and paperboard intended to contact food.

DATES: Written comments on the petitioner’s environmental assessment by June 19, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 1240 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St., S.W., Washington, DC 20204-0002, 202-418-3080.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(1) (2) U.S.C. 348(b)(1)(ii)), notice is given that a food additive petition (FAP 384478) has been filed by Albrit & Wilson, Ltd. to Delta Analytical Corp., 710 Woodment Ave., suite 1000, Bethesda, MD 20814. The petition proposes to amend the food additive regulations in section 176.300 in subpart C (176.309) to provide for the safe use of tertahydroxymethylphosphonium sulfamate as a stimulant in the manufacture of paper and paperboard intended to contact food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501-1507), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before June 19, 1996, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments or to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner’s environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency’s finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 23.40c.

Dated: April 30, 1996.

Alan M. Rubia, Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition (FRS-200), P.O. Box 1133, Silver Spring, MD 20910-1133.

[Docket No. 93F-0148]

Wincorp., Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to future filing, of a food additive petition (FAP 384348), filed by Wincorp., proposing that the food additive regulations be amended to provide for the safe use of decanediol acid, polymer with 1.2-ethanediol (E.D. 9.12)-octadecylamine acid dimer and 4'- (1.3-propenylidene) bis (piperylamine) as a polymer coating on aluminum foil, polyvinyl film and paper and paperboard and as an adhesive, for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Homer S. Macon, Center for Food Safety and Applied Nutrition (HFS-210), Food and Drug Administration, 200 C St., S.W., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of May 19, 1993 (58 FR 29221), FDA announced that a food additive petition (FAP 383438) had been filed by WinCorp., 7117 Freeman Rd., P.O. Box 648, Dublin, OH 43017. The petition proposed to amend the food additive regulations to provide for the safe use of decanediol acid, polymer with 1.2-ethanediol (E.D. 9.12)-octadecylamine acid dimer and 4'- (1.3-propenylidene) bis (piperylamine) as a polymer coating on aluminum foil, polyvinyl film, and paper and paperboard and as an adhesive, for use in contact with food. Wincorp., has now withdrawn the petition without prejudice to a future filing (21 CFR 1.7).

Dated: April 30, 1996.

Alan M. Rubia, Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition (FRS-200), P.O. Box 1133, Silver Spring, MD 20910-1133.

[Docket No. 93F-0112]

SmithKline Beecham Pharmaceuticals; Notice of Approval of a New Drug Application for Salacycin Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for Salacycin Tablets (SmithKline Beecham Pharmaceuticals, Harrah, OH). SmithKline Beecham Pharmaceuticals (SmithKline) requested that the NDA be withdrawn because the product is no longer being marketed. SmithKline also waived its opportunity for a hearing.

EFFECTIVE DATE: May 20, 1996.

FOR FURTHER INFORMATION CONTACT: Lola E. Baron, Center for Drug Evaluation and Research (HFS-71), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1038.

SUPPLEMENTARY INFORMATION: By letter dated June 30, 1994, SmithKline, Four Falls Corp., Center, Route 23, and Woodmont Ave., P.O. Box 1510, Fairfield, PA 19014, requested that FDA withdraw NDA 18-103 for Salacycin (tricycloumen) Tablets stating that the company discontinued trade of the product.
marketing the product in 1980 because of liver toxicity observed after approval of the NDA. SmithKline waived its opportunity for a hearing.

Attention is called to section 305(g)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and comments are invited, in writing, upon the following:

FDA: Office of Food and Drug Administration, Attention: Consumer Information Center. Dockets: FAX G-1194j (FDA).

In compliance with the requirement of section 350(i)(2)(A) of the Paperwork Reduction Act of 1980, the Federal Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed studies for public comment: Interested persons are invited to send comments pertaining to this burden, estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: New Collection. Title of Information Collection: Evaluation of the Oregon Medicaid Reform Demonstration: Adult Interview, Child Interview, Pediatric Asthma Interview, Insulin-Dependent Diabetes Interview, Low Back Pain Interview, Medical Provider Questionnaire. Setting: Oregon Medicaid Reform Demonstration. The Adult and Child Interview are designed to collect information related to health status, access to care, satisfaction with care and health insurance status for adult and child members of the Oregon Health Plan (OHP), the Pediatric Asthma Interview, Insulin-Dependent Diabetes Interview and Low Back Pain Interview collect information on quality of care, satisfaction of care, satisfaction with care and health status of OHP members with selected "tracer" conditions. The Medical Provider Questionnaire is designed to collect information on how participating and non-participating physicians view OHP. Frequency: Bi-annually. Other time: one-time. Affected Public: Not-for-profit institutions, individuals and households, business or other for-profit. Number of Respondents: 22,239. Total Annual Hours: 3,070.

2. Type of Information Collection Request: Revisions to: Revisions to: Title of Information Collection: Evaluation of the Oregon Medicaid Reform Demonstration: Adult Interview, Child Interview, Pediatric Asthma Interview, Insulin-Dependent Diabetes Interview, Low Back Pain Interview, Medical Provider Questionnaire. Setting: Oregon Medicaid Reform Demonstration. The Adult and Child Interview are designed to collect information related to health status, access to care, satisfaction with care and health insurance status for adult and child members of the Oregon Health Plan (OHP), the Pediatric Asthma Interview, Insulin-Dependent Diabetes Interview and Low Back Pain Interview collect information on quality of care, satisfaction of care, satisfaction with care and health status of OHP members with selected "tracer" conditions. The Medical Provider Questionnaire is designed to collect information on how participating and non-participating physicians view OHP. Frequency: Bi-annually. Other time: one-time. Affected Public: Not-for-profit institutions, individuals and households, business or other for-profit. Number of Respondents: 22,239. Total Annual Hours: 3,070.

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8. Type of Information Collection Request: Revisions to: Revisions to: Title of Information Collection: Evaluation of the Oregon Medicaid Reform Demonstration: Adult Interview, Child Interview, Pediatric Asthma Interview, Insulin-Dependent Diabetes Interview, Low Back Pain Interview, Medical Provider Questionnaire. Setting: Oregon Medicaid Reform Demonstration. The Adult and Child Interview are designed to collect information related to health status, access to care, satisfaction with care and health insurance status for adult and child members of the Oregon Health Plan (OHP), the Pediatric Asthma Interview, Insulin-Dependent Diabetes Interview and Low Back Pain Interview collect information on quality of care, satisfaction of care, satisfaction with care and health status of OHP members with selected "tracer" conditions. The Medical Provider Questionnaire is designed to collect information on how participating and non-participating physicians view OHP. Frequency: Bi-annually. Other time: one-time. Affected Public: Not-for-profit institutions, individuals and households, business or other for-profit. Number of Respondents: 22,239. Total Annual Hours: 3,070.

9. Type of Information Collection Request: Revisions to: Revisions to: Title of Information Collection: Evaluation of the Oregon Medicaid Reform Demonstration: Adult Interview, Child Interview, Pediatric Asthma Interview, Insulin-Dependent Diabetes Interview, Low Back Pain Interview, Medical Provider Questionnaire. Setting: Oregon Medicaid Reform Demonstration. The Adult and Child Interview are designed to collect information related to health status, access to care, satisfaction with care and health insurance status for adult and child members of the Oregon Health Plan (OHP), the Pediatric Asthma Interview, Insulin-Dependent Diabetes Interview and Low Back Pain Interview collect information on quality of care, satisfaction of care, satisfaction with care and health status of OHP members with selected "tracer" conditions. The Medical Provider Questionnaire is designed to collect information on how participating and non-participating physicians view OHP. Frequency: Bi-annually. Other time: one-time. Affected Public: Not-for-profit institutions, individuals and households, business or other for-profit. Number of Respondents: 22,239. Total Annual Hours: 3,070.
January 16, 1980

VITAL: DRUG RECALL

Dear Doctor:

Clinical use of SelacrIn® (brand of ticrynafen) has shown that the drug can cause significant hepatic injury. The injury is of the hepatocellular type. The 52 reports received thus far have been characterized by fever and elevation of serum transaminase levels, with jaundice in about 60% of these cases. A few instances of severe hepatic damage and death have been noted, but no definite causal relationship to 'SelacrIn' administration has yet been established in these cases. No precise incidence figures for this adverse effect is available; the 52 reports have arisen in an exposed population of about 300,000 patients, which would represent an incidence of about 1 in 5,000. However, this is likely to be an underestimate as adverse effects tend to be underreported.

Because alternative treatments for hypertension and congestive heart failure are available, sale of 'SelacrIn' has been suspended.

YOU SHOULD DISCONTINUE USE OF 'SELACRIN' IMMEDIATELY AND CONTACT PATIENTS WHO HAVE BEEN GIVEN 'SELACRIN'.

If a patient has symptoms that could suggest hepatic injury (fever, malaise, nausea, abdominal pain), assessment of liver function is appropriate. Any significant findings should be reported to us to assist in determining the frequency of hepatic injury. You may wish to evaluate liver function even in the absence of symptoms.

Commercial supplies of the drug are being recalled from retail and hospital pharmacies and wholesalers.

Sincerely,

Philip J. Tannenbaum, M.D.
Vice-President & Medical Director-U.S.
SMITH KLINE & FRENCH LABORATORIES
150 East Jackson Blvd, P.O. Box 7929, Philadelphia, Pa. 19101; 215-626-0000

January 16, 1980

URGENT: DRUG RECALL

Dear Pharmacist:

Smith Kline & French Laboratories is recalling Selacyrn® (brand of tiacrynafen). You will be contacted shortly with specific details about procedures to be followed for the recall.

The enclosed letter is being sent to physicians in your community. It reports the occurrence of a hypersensitivity reaction involving the liver which has prompted the decision to suspend sale of 'Selacyrn'.

We have alerted you in the hope that you may assist clinics, outpatient departments, and other areas of your hospital in identifying 'Selacyrn' patients. The physician can then contact the patient and take appropriate steps.

Thank you for your attention and cooperation.

Sincerely,

[Signature]

Joseph L. Rutledge
Vice President, Trade Relations

JLR:ctap
Enclosure